

**REMARKS**

**I. Status of the Claims**

Claims 1-9, 13-20, 24-26, 29, 31, 33, 35, 37-48, 151, and 152 are pending in the application. No claims have been amended.

**II. Claim Rejections under 35 U.S.C. § 112, first paragraph**

Claims 6, 7, and 31 are rejected under 35 U.S.C. § 112, first paragraph for allegedly failing to satisfy the written description requirement. Office Action at pp. 2-3. Applicants respectfully traverse this rejection.

The Examiner asserts that "the issue is not with the derivatives per se but with derivatives as it defines polysaccharide polymers." *Id.* at p. 2. According to the Examiner, "one of ordinary skill in the art is expected to experiment with all known and yet to be discovered derivatives of polysaccharide polymers ... and identify the derivatives that would work in applicants' invention." *Id.* at pp. 2-3.

The standard for written description under 35 U.S.C. § 112, first paragraph is whether the specification conveys "with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention." M.P.E.P. § 2163.02; see, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). It is not necessary that the claimed subject matter be described literally. M.P.E.P. § 2163.02. There is a **strong presumption** that an adequate written description of the claimed invention is present in the specification as filed. M.P.E.P. § 2163.03; *In re Wertheim*, 541 F.2d 257, 262 (CCPA 1976).

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Applicants respectfully submit that if the meaning of "derivative" is not at issue, and the meaning of "polysaccharide polymers," or "cationic starch," etc. is not at issue, then the phrases asserted by the Examiner should not be rejected.

Moreover, because of the strong presumption of adequate written description of an originally filed claim, the M.P.E.P. acknowledges that "rejection of an original claim for lack of written description should be rare." M.P.E.P. § 2163.03. Typical reasons for rejecting a claim for lack of written description are:

- I. Amendment affecting a claim;
- II. Reliance on filing date of parent application under 35 U.S.C. § 120;
- III. Reliance on Priority under 35 U.S.C. § 119; and
- IV. Support for a claim corresponding to a count in an interference.

Applicants respectfully submit that none of these aspects are at issue here.

The M.P.E.P. outlines the burden on the Examiner with regard to the written description requirement.

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption.

M.P.E.P. § 2163.04 (added emphasis). Moreover, the M.P.E.P. explicitly states:

In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion ... A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

M.P.E.P. § 2163.04.I (added emphasis). Unpredictability, however, is essentially the basis for the rejection here. By presenting the issue as whether "one of ordinary skill in the art is expected to experiment with all known and yet to be discovered derivatives of

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polysaccharide polymers ..." (Office Action at p. 2), the Examiner is effectively offering a conclusory statement that the art is unpredictable. As expressly stated in the M.P.E.P., such conclusory statements do not comport with the sufficient evidence or reasoning required to overcome the strong presumption of adequate written description of the claims as originally filed.

Accordingly, Applicants respectfully submit that this rejection under 35 U.S.C. § 112, first paragraph, is in error and respectfully request that the rejection be withdrawn.

**III. Rejection under 35 U.S.C. § 112, second paragraph**

Claims 6, 7, and 31 are rejected under 35 U.S.C. § 112, second paragraph for indefiniteness. Office Action at pp. 3-4. Applicants respectfully traverse the rejection.

The Examiner continues to reject claims based on the use of the word "derivative." The Examiner questions "[w]hat are the derivatives ... of polysaccharide polymers ...?" *Id.* at p. 3.

In determining whether the claims describe the subject matter with a reasonable degree of clarity and particularity, the following must be considered:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made.

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M.P.E.P. § 2173.02. Thus, definiteness is determined from the point of view of one of ordinary skill in the art. *Id.* ("[T]he examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope.").

Applicants respectfully maintain that one of ordinary skill in the art would be readily apprised of the scope of the claims, would understand what is meant by the term "derivatives" as used in the present application, and would therefore understand the metes and bounds of the presently claimed invention. When properly analyzed in light of the claim language, the content of the specification, and the teachings of the prior art, the term "derivatives" clearly defines the subject matter that Applicants consider within the scope of their invention with reasonable particularity and precision.

In support of their position, Applicants submit herewith another dictionary definition p. 375 from The American Heritage College Dictionary (Third Edition), which defines the noun "derivative" as "[a] compound derived or obtained from another and containing the essential elements of the parent substance," and defines the verb "derive" as "[t]o produce or obtain (a compound) from another substance by chemical reaction."

Thus, because "derivative" is sufficiently definite, and the meaning of polysaccharide polymers, cationic starches, cationic gums, and C<sub>5</sub> to C<sub>7</sub> saccharide units is sufficiently clear, it necessarily follows then that the derivatives of these compounds are also sufficiently definite. Applicants respectfully maintain that the Examiner has set forth no evidence to show that these phrases would be viewed as indefinite from the point of view of one of ordinary skill in the art.

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Accordingly, Applicants respectfully assert that, in light of the language of all the claims, the specification, and the teachings of the prior art, what is meant by the term "derivatives" is clear. Accordingly, Applicants respectfully submit that this reason for rejection is in error and request that this rejection be withdrawn.

**IV. Claim Rejections under 35 U.S.C. § 102**

Claims 1-9, 16, 17, 19, 20, 24-26, 29, 31, 33, 35, 45, 46, and 47 are rejected under 35 U.S.C. is § 102(b) as anticipated by U.S. Patent No. 5,597,811 ("*Gruber*"). Office Action at pp. 4-5. The Applicants respectfully traverse the rejection.

The Examiner asserts that picking and choosing is not required to show that *Gruber* anticipates the claims. *Id.* at p. 4. Moreover, the Examiner also believes *Gruber* anticipates the claims because the claims "do not recite any effective amounts." *Id.* at p. 5.

A rejection under § 102 is only proper when the claimed subject matter is identically described or disclosed in the prior art. *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972); see also M.P.E.P. § 706.02(a) ("For anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly."). Importantly, each and every element of a claim must be set forth in the prior art reference for there to be anticipation. See M.P.E.P. § 2131.

Applicants respectfully maintain that one must pick and choose from isolated passages in *Gruber* to arrive at the claimed invention. *Gruber* does not disclose the identical composition, as claimed. Rather, *Gruber* presents a series of options. First, one must select to use a mousse from a list of personal care compositions. See col. 7,

lines 62-67. Even upon selecting a mousse, one must select between "a resin like polyquaternium-10 or poly(vinylmethacrylate)/methacrylate copolymer." If the latter were chosen, the resulting composition would not anticipate the claims. Thus, Gruber does not provide the specific guidance needed to describe the "identical invention ... in as complete detail as is contained in the ... claim." M.P.E.P. § 2131; *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989).

Moreover, Applicants respectfully disagree with the Examiner's statement that "the claims rejected under 35 USC 102 do not recite any effective amounts." See Office Action at p. 5. The Federal Circuit has construed claims reciting "sufficient pharmaceutically active drug to deliver ... a pharmaceutically effective amount" where the specification failed to explicitly provide exemplary amounts. See *Key Pharmaceuticals v. Hercon Laboratories*, 161 F.3d 709 (Fed. Cir. 1998) (where the Federal Circuit construed this term from extrinsic evidence, such as minimum dosages approved by the FDA). The present case offers more than the patentees in *Key Pharmaceuticals*; the claims explicitly recite that the at least one compound (a) and the at least one compound (b) "are present in an amount effective to durably condition." The specification provides exemplary effective amounts at p. 15, lines 11-14, and at p. 18, lines 16-19. When reading the claims in light of the specification, one of ordinary skill in the art would view the present claims as reciting effective amounts. Thus, to anticipate the present claims, Gruber must disclose amounts effective to durably condition the at least one keratinous fiber.

Accordingly, Applicants respectfully submit that the rejection under 35 U.S.C. § 102 has been overcome and request that the rejection be withdrawn.

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V. Claim Rejections under 35 U.S.C. § 103

Dunlop, Gruber and Yoshihara

Claims 1-9, 13-20, 24-26, 29, 31, 35, and 37-48 are rejected under 35 U.S.C. § 103(a) as unpatentable over U.S. Publication No. 2002/0102228 ("*Dunlop*") in view of U.S. Patent No. 5,597,811 ("*Gruber*") and further in view of U.S. Patent No. 5,332,581 ("*Yoshihara*"). Office Action at pp. 5-6. Applicants respectfully traverse this rejection.

In order to establish a *prima facie* case of obviousness, the Examiner must demonstrate that there is some suggestion or motivation, either in the cited references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify a reference or combine reference teachings. See M.P.E.P. § 2143.

To support the combination of references, the Examiner states that "both [Dunlop and Yoshihara] compositions are used for hair treatment" and both the Gruber and Dunlop compositions "are used for the same purpose." Office Action at p. 6. Applicants respectfully submit that these are insufficient premises to support a *prima facie* case of obviousness. Evidence of a suggestion or motivation to modify or combine references teachings must be "clear and particular." *In re Dembiczak*, 175 F.3d 994, 999 (Fed. Cir. 1999). A very broad-based, generalized rationale, as provided here, does not comply with the "clear and particular" standard set forth by the Federal Circuit. Moreover, the mere citation of *In re McLaughlin* does not circumvent the well-settled requirement of showing a suggestion or motivation to combine references. No case citation can "outweigh the dozens of rulings of the Federal Circuit and the Court of Customs and

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Patent Appeals that determination of patentability must be based on evidence." See *In re Lee*, 277 F.3d 1338, 1345 (Fed. Cir. 2002) (added emphasis).

Applicants respectfully continue to maintain that the combination is improper. *Dunlop* lists very rigid requirements for an effective shampoo: (1) bioavailability and coverage of the anti-dandruff active for anti-dandruff efficacy; (2) comb-ability of wet hair and (3) clean hair feel; and (4) the inherent ability of the anti-dandruff active to inhibit the growth of microorganisms. Paragraph [0009]. *Dunlop's* shampoo composition further depends on the level and type of cationic polymer employed in the composition, the type of anti-dandruff agent employed, the amount of anionic surfactant employed. Paragraph [0010]. In light of *Dunlop's* rigid requirements discussed above, *Dunlop* cannot be combined with *Yoshihara* without a clear suggestion to do so. The Examiner relies on *Yoshihara's* teaching of heating the compositions at 30°C to 50°C for 10 to 35 minutes upon applying the composition to the hair. Office Action at p. 6; see also *Yoshihara* col. 5, l. 52-57. *Yoshihara* is directed to a composition very different from that of *Dunlop* comprising a "specific dialkylene glycol monoalkyl ether" combined with a "specific aromatic alcohol derivative and an acid." Col. 1, l. 37-45. While the heat treatment step of *Yoshihara* may work for *Yoshihara's* compositions, there is no teaching or suggestion that it will apply to *Dunlop's* shampoo. A heat treatment may "impair product stability, aesthetics or performance" of *Dunlop's* compositions. See *Dunlop*, paragraph [0118].

"When the applicant traverses any rejection, the examiner should, if he or she repeats the rejection, take note of the applicants' argument and answer the substance of it." M.P.E.P. § 707.07(f). This has not been done here. The Examiner has not

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responded, with evidence, to show how there is a suggestion to heat treat *Dunlop's* shampoo without a suggestion to do so.

*Dunlop* also cannot be combined with *Gruber* without a clear suggestion. First, the composition of *Dunlop* and the composition of *Gruber* are directed toward very different objectives. *Dunlop* teaches anti-dandruff shampoos, whereas, *Gruber*, in the example cited by the Examiner, teaches a mousse. Moreover, in light of *Dunlop's* rigid requirements, there is no clear teaching that the ingredients in *Gruber's* mousse will work in *Dunlop's* anti-dandruff shampoo. Finally, Applicants contend that *Gruber* does not teach the claimed compounds in effective amounts to achieve durable conditioning, as alleged.

The combination is thus premised on hindsight, where individual components from different disclosures are combined without a suggestion to do so. Instead, Applicants' claims have been used as a template in order to arrive at the combination of references. Applicants respectfully submit that a *prima facie* case has not been established and request that the rejection be withdrawn.

#### **Dunlop and Rath**

Claims 151 and 152 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Publication No. 2002/0102228 ("*Dunlop*") in view of U.S. Patent No. 5,993,792 ("*Rath*"). Office Action at p. 6. Applicants respectfully traverse this rejection.

The Examiner states that "there is no recitation of the order of the first or second" compartment. *Id.* Applicants respectfully submit that "order" was not the substance of

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their argument in the previous Reply. Rather, independent claim 151 requires a first compartment comprising at least one compound comprising at least two quaternary ammonium groups, and a second compartment comprising at least one C<sub>5</sub> to C<sub>7</sub> saccharide unit substituted with at least one amino group. Thus, the claimed kit maintains the claimed quaternary ammonium-containing compound separately from the claimed saccharide-containing compound. The references, in contrast, do not teach separating these ingredients. If anything, *Dunlop* teaches shampoos packaged as a single formulation. There is no suggestion or motivation to modify *Dunlop* to package ingredients separately. Although *Rath* teaches a kit comprising separated components, *Rath* does not require that the claimed saccharide compound be separate from the claimed quaternary ammonium compound. Rather, *Rath* motivates one of ordinary skill in the art to package a formulation by separating a thickener from the shampoo base. Thus, even if for the sake of argument, *Dunlop* and *Rath* could be combined, the combined teachings would not guide one of ordinary skill in the art to the claimed invention because there is no suggestion to separate the claimed quaternary ammonium-containing compound from the claimed saccharide-containing compound.

Applicants respectfully submit that a *prima facie* case has not been established and request that the rejection be withdrawn.

**Gruber and Applicants' specification**

Claims 14, 15, and 39-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,597,811 ("*Gruber*") in view of applicant's allegedly

admitted prior art. Office Action at pp. 6-7. Applicants respectfully traverse this rejection.

Applicants had previously submitted that this combination was improper because Gruber does not teach that its mousses would benefit from the properties of sugars, as discussed in Applicants' specification. In response, the Examiner states "future intended use is not critical. *Id.* at p. 7. Applicants respectfully submit that their argument was not intended to distinguish the combination from the claims, but to show that the combination is improper. Thus, Gruber's failure to suggest the need for sugars shows that there is no suggestion or motivation to add sugars. Because the combination is improper, Applicants do not even need to distinguish the combination from the claims.

The Examiner continues to maintain that "it is not inventive to discover the optimum workable ranges by routine experimentation." Office Action at p. 8. Applicants had previously submitted that "a particular parameter must first be recognized as a result-effective variable ... before the determination of the optimum or workable ranges... might be characterized as routine experimentation." M.P.E.P. § 2144.05.II.B; *in re Antonie*, 559 F.2d 618 (C.C.P.A. 1977). Because none of the references teach a composition comprising the claimed compounds, the amounts recited in claims 14, 15, 43, and 44 could not have been determined by routine experimentation. Again, the Examiner is required to respond to the substance of this argument, as required by M.P.E.P. § 707.07(f).

Applicants respectfully submit that a *prima facie* case has not been established and request that the rejection be withdrawn.

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VI. Conclusion

In view of the foregoing remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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